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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,385

04/13/2006

Marcus A. Horwitz

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7590

08/11/2008

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,385	<b>Applicant(s)</b> HORWITZ ET AL.	
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16-24, 26-32 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 16-24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32 and 41-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group II, claims 27-32 and 41-43 in the reply filed on July 9, 2008 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 27-32 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Horwitz et al

The applied reference has a common inventor (Marcus Horwitz and Gunter Harth) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are directed to a prime boost vaccine strategy comprising administering a first priming immunogenic composition to a vaccinee wherein said first priming immunogenic composition is a BCG; administering a second boosting immunogenic composition, after the passage of a period of time, to said vaccinee optionally in the presence of an adjuvant, wherein said second boosting immunogenic composition is a purified Mycobacteria major extracellular protein; and wherein a protective immune response results in said vaccinee.

Horwitz et al (US Patent Number 6,471,967) disclose of injecting intradermally 10 µg of purified recombinant M. tuberculosis 30 kDa major extracellular non-fusion protein, nine weeks after immunization with BCG. (See column 15).

2. Claims 27-31 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Orme et al.

The claims are directed to a prime boost vaccine strategy comprising administering a first priming immunogenic composition to a vaccinee wherein said first priming immunogenic composition is a BCG; administering a second boosting immunogenic composition, after the passage of a period of time, to said vaccinee optionally in the presence of an adjuvant, wherein said second boosting immunogenic composition is a purified Mycobacteria major extracellular protein; and wherein a protective immune response results in said vaccinee.

Orme et al (US Patent Number 7,288,261) disclose of vaccine compositions for boosting immunity to mycobacteria when administered in mide life in a subject who has

been vaccinated with BCG. Orme et al further disclose that a preferred protein for boosting is Ag85A, a secreted Mycobacteria major extracellular protein having a molecular weight of 30 kDa. (See abstract and claims).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 27-32 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horwitz et al in view of Orme et al.

The claims are directed to a prime boost vaccine strategy comprising administering a first priming immunogenic composition to a vaccinee wherein said first

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priming immunogenic composition is a BCG; administering a second boosting immunogenic composition, after the passage of a period of time, to said vaccinee optionally in the presence of an adjuvant, wherein said second boosting immunogenic composition is a purified Mycobacteria major extracellular protein; and wherein a protective immune response results in said vaccine, and wherein the BCG over expresses a Mycobacteria major extracellular protein of 30 kDa.

Horwitz et al (PNAS Vol. 97, No. 25, pp 13853-13858, December 5, 2000) teach that recombinant BCG vaccines which express the Mycobacterium tuberculosis 30 kDa major secretory protein induced greater protective immunity against tuberculosis than conventional BCG vaccines in a highly susceptible animal model. (See abstract).

Horwitz et al further teach that "immune response to the 30 kDa protein may be a critical factor in protective immunity to TB." (See page 13858).

Horwitz et al do not teach of administering a second boosting immunogenic composition which is a purified Mycobacteria major extracellular protein.

Orme et al (US Patent Number 7,288,261) teach of vaccine compositions for boosting immunity to mycobacteria specifically for individuals who were previously vaccinated with BCG. (See abstract). Orme et al reports that adults vaccinated with BCG as young children become relatively unprotected. (See summary).

Given that Horwitz et al teach of the superiority of a recombinant BCG vaccine which expressed the Mycobacterium tuberculosis 30 kDa major secretory protein, and that 2) Orme et al teach of vaccine compositions for boosting the immune response to Mycobacteria, and specifically teach of the 30 kDa major secretory protein for

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administration to individuals vaccinated with BCG, it would have been prima facie obvious to have incorporated the step of administering a 30 kDa major secretory protein as taught by Orme et al with the method of vaccination as taught by Horwitz et al. One would have been motivated to add the booster step in view of the teaching by Orme et al that adults vaccinated with BCG as young children become relatively unprotected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
August 6, 2008